PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	08 DEC 2004
Applicant's or agent's file reference FP71973TAL (CYO/JCB)	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US04/12066	19 April 2004 (19.04.2004)	17 April 2003 (17.04.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 38/00, 48/00 and US Cl.: 514/2,44

Rspn to Written Opinion due 3/08/05 JB

Applicant

MOUNT SINAI SCHOOL OF MEDICINE NEW YORK UNIVERSITY

1. This opinion contains indications relating to the following items:

- [x] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [x] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Jon Eric Angell Telephone No. 703-308-1235

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/12066

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☒ table(s) related to the sequence listing

   b. format of material

      ☒ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/12066

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-15	YES
	Claims 16-47	NO
Inventive step (IS)	Claims 1-15	YES
	Claims 16-47	NO
Industrial applicability (IA)	Claims 1-47	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 16-47 lack novelty under PCT Article 33(2) as being anticipated by KUBOTA. The instant claims are drawn to a method of inhibiting the growth of a tumor cell, inhibiting an inflammatory reaction, and treating an autoimmune disease by administering Mumps virus V protein (or a polynucleotide sequence encoding said protein) to a subject. KUBOTA teaches that Mumps virus V protein, and specifically interacts with RACK1 protein to inhibit STAT1 activity, thus interrupting the alpha interferon signal transduction pathway. Alpha interferon signaling was known to be critically involved in tumor, and immune system activities. Therefore, using the reference teaches that administering mumps virus V protein (or a polynucleotide encoding said protein) would be an effective treatment for tumors, inflammatory reactions and autoimmune disease.

Claims 16-47 lack novelty under PCT Article 33(2) as being anticipated by YOKOSAWA. The instant claims are drawn to a method of inhibiting the growth of a tumor cell, inhibiting an inflammatory reaction, and treating an autoimmune disease by administering Mumps virus V protein (or a polynucleotide sequence encoding said protein) to a subject. YOKOSAWA teaches that the Mumps virus V protein can inhibit STAT1 activity, and that this inhibition does not require the C-terminal region of STAT-1alpha. Interferon signaling through STAT1 was known to be critically involved in tumor, and immune system activities. Therefore, using the reference teaches that administering mumps virus V protein (or a polynucleotide encoding said protein) would be an effective treatment for tumors, inflammatory reactions and autoimmune disease.

It is noted that the ULANE reference was published after the claimed priority date. Since the claimed priority is accepted, the reference is not considered prior art.

Claims 1-15 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of modulating STAT3 mediated signaling in a cell by administering mumps virus V protein (SEQ ID NO: 1), or a nucleic acid encoding mumps virus v protein, to a cell.

Claims 1-47 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.